

PTO/SB/21 (05-03)

Approved for use through 04/30/2003. OMB 0651-0031

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Application Number

10627358

Filing Date

July 25, 2003

First Named Inventor

Peter Migaly

Art Unit

Examiner Name

Attorney Docket Number

290194-00001

Total Number of Pages in This Submission

**ENCLOSURES (Check all that apply)**

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Debra Z. Anderson

Signature

Date

February 11, 2004

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: :  
: :  
PETER MIGALY : COMBINATION THERAPY FOR  
: DEPRESSION, PREVENTION OF  
Filed: July 25, 2003 : SUICIDE, AND VARIOUS MEDICAL  
: AND PSYCHIATRIC CONDITIONS  
Attorney Docket No.: 290194-00001 :

**INFORMATION DISCLOSURE STATEMENT**

February 11, 2004

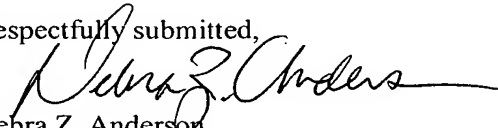
Mail Stop PATENT APPLICATION  
Commissioner for Patents  
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Alexandria, Virginia 22313

Sir:

Pursuant to the provisions of 37 CFR Sections 1.56, 1.97 and 1.98, Applicant submits herewith copies of the foreign patent document references and non-patent literature document references cited on the attached Forms PTO/SB/08A and PTO/SB/08B for consideration during prosecution of this application.

This Statement is filed solely for the purpose of complying with the pertinent rules of the Office and is not intended to be a substitute for an independent evaluation by the Examiner of the art cited or an independent search by the Examiner, and no representation of any nature is made or intended by the filing of this Statement.

Respectfully submitted,

  
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PTO/SB/08A (08-00)  
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|   |   |           |   | <b>Application Number</b>                  |  |
|   |   |           |   | <b>Filing Date</b> July 25, 2003           |  |
|   |   |           |   | <b>First Named Inventor</b> Peter Migaly   |  |
|   |   |           |   | <b>Group Art Unit</b>                      |  |
|   |   |           |   | <b>Examiner Name</b>                       |  |
| <b>Sheet</b>  | 1 | <b>of</b> | 3 | <b>Attorney Docket Number</b> 290194-00001 |  |

| U.S. PATENT DOCUMENTS |                          |                      |                                      |  |  |  |
|-----------------------|--------------------------|----------------------|--------------------------------------|--|--|--|
| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | U.S. Patent Document |                                      | Name of Patentee or Applicant<br>of Cited Document | Date of Publication of<br>Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear |
|                       |                          | Number               | Kind Code <sup>2</sup><br>(if known) |  |  |  |
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|-----------------------------------|--------------------------|-------------------------|---------------------|--------------------------------------|--|--|--|----------------|
| Examiner<br>Initials <sup>*</sup> | Cite<br>No. <sup>1</sup> | Foreign Patent Document |                     |                                      | Name of Patentee or<br>Applicant of Cited Document | Date of Publication of<br>Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>6</sup> |
|                                   |                          | Office <sup>3</sup>     | Number <sup>4</sup> | Kind Code <sup>5</sup><br>(if known) |  |  |  |                |
|                                   | U                        | WO                      | 99/61027            |                                      | Eli Lilly and Co                                   | 12-02-1999   |  |                |
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|                                   | Z                        | WO                      | 01/51040            |                                      | Laboratorios Ph                                    | 07-19-2001   |  |                |
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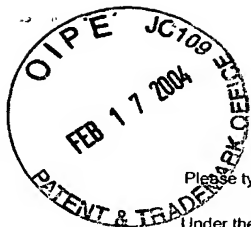
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 3

### Complete if Known

|                        |               |
|------------------------|---------------|
| Application Number     |               |
| Filing Date            | July 25, 2003 |
| First Named Inventor   | Peter Migaly  |
| Group Art Unit         |               |
| Examiner Name          |               |
| Attorney Docket Number | 290194-00001  |

### OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

| Examiner Initials <sup>1</sup> | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.   | T <sup>2</sup> |
|--------------------------------|-----------------------|---|----------------|
|                                | AC                    | MICHAEL E. THASE, M.D.; "What Role Do Atypical Antipsychotic Drugs Have in Treatment-Resistant Depression?"; The Journal of Clinical Psychiatry; February, 2002; Pages 95-103; 63:2; Physicians Postgraduate Press, Inc., Memphis, Tennessee  |                |
|                                | AD                    | JAMBUR ANANTH; "Treatment-Resistant Depression"; Psychother Psychosom; 1998; Pages 61-70; 67; S. Karger AG, Basel, Switzerland  |                |
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|                                | AH                    | SHIGEHIO HIROSE, M.D. and CHARLES R. ASHBY, JR., PH.D.; "An Open Pilot Study Combining Risperidone and a Selective Serotonin Reuptake Inhibitor as Initial Antidepressant Therapy"; Journal of Clinical Psychiatry; August, 2002; Pages 733-736; 63:8; Physicians Postgraduate Press, Inc., Memphis, TN |                |
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